



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

November 2, 2016

Exactech, Incorporated  
Lindy Knisely, RN  
Regulatory Affairs Specialist  
2320 N.W. 66<sup>th</sup> Court  
Gainesville, Florida 32653

Re: K110708

Trade/Device Name: Exactech® Equinox® Reverse Shoulder System™  
Regulation Number: 21 CFR 888.3660  
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis  
Regulatory Class: Class II  
Product Code: PHX, KWS, KWT  
Dated: March 11, 2011  
Received: March 14, 2011

Dear Ms. Knisely:

This letter corrects our substantially equivalent letter of April 1, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Lori A. Wiggins -S**

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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**Exactech® Equinox® Reverse Shoulder™ Line Extensions  
Special 510(k) – Indications for Use**

**510(k) Number:** K110708

**Device Name(s): Exactech® Equinox® Reverse Shoulder System™**

The Equinox Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemi-arthroplasty is determined by the surgeon to be the preferred method of treatment.

- The cemented primary humeral stem, long/revision stem, fracture stems and all Equinox glenoids are intended for cemented fixation.
- The press-fit humeral stems are intended for press-fit applications but may be used with bone cement at the discretion the surgeon.
- The reverse humeral components are intended to be used in cemented applications or in revision cases when the humeral component is well-fixed/stable, as deemed by the orthopaedic surgeon.
- Humeral Heads are intended for use in cemented and press-fit applications.

Clinical indications for the PRIMARY (P), LONG/REVISION (L), and FRACTURE (F) humeral components are as follows:

P	L	F	Indications
✓	✓		Rheumatoid arthritis, osteoarthritis, osteonecrosis or post-traumatic degenerative problems
✓	✓		Congenital abnormalities in the skeletally mature
✓			Primary and secondary necrosis of the humeral head.
✓		✓	Humeral head fracture with displacement of the tuberosities
✓	✓		Pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
✓	✓		Revisions of humeral prostheses when other treatments or devices have failed (where adequate fixation can be achieved)
		✓	Displaced three-part and four-part upper humeral fractures
	✓		Spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases)
	✓		Revision of failed previous reconstructions when distal anchorage is required
✓	✓		To restore mobility from previous procedures (e.g. previous fusion)

The Equinox Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinox Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

The Equinox Platform Fracture Stem is indicated for use in skeletally mature individuals with acute fracture of the proximal humerus and displacement of the tuberosities, displaced 3- and 4-part fractures of the proximal humerus (hemi-arthroplasty), or acute fracture of the proximal humerus with failure of the glenohumeral joint (primary total shoulder arthroplasty). The Equinox Platform Fracture Stem is also indicated for acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty). The Equinox Platform Fracture Stem is indicated for cemented use only.

**Prescription Use**   X   **and/or** **Over-The-Counter Use**             
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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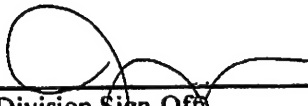
*CORH/ODE concurrence  
on next page JMD 3*

Exactech® Equinox® Reverse Shoulder™ Line Extensions  
Special 510(k) – Indications for Use

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Concurrence of CDRH, Office of Device Evaluation (ODE)

 for M. McKersin  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K110708

**Exactech® Equinox® Reverse Shoulder™ Line Extensions**  
**Special 510(k) - Section 07 - 510(k) Summary**

**I. Submitter Information**

**Company:** Exactech, Inc  
2320 N.W. 66<sup>th</sup> Court  
Gainesville, Florida 32653

**Date:** March 11, 2011

**Contact Person:** Lindy Knisely, RN  
Regulatory Affairs Specialist  
Telephone: (352) 377-1140  
Fax: (352) 378-2617

**II. Device Information**

**Proprietary Name:** Exactech Equinox® Reverse Shoulder™

**Common Name:** Laterally Offset Glenospheres  
Posterior Augment Glenoid Plate  
Superior Augment Glenoid Plate  
Extended Cage Glenoid Plate  
Compression Screws

**Classification Name:** Prosthesis, Shoulder, Non-Constrained, Metal/Polymer  
Cemented (21 CFR 888.3650 [Shoulder joint  
metal/polymer non-constrained cemented prosthesis], Class  
II, Product Code KWT)

Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer  
Cemented (21 CFR 888.3660 [Shoulder joint  
metal/polymer semi - constrained cemented prosthesis],  
Class II, Product Code KWS)

**III. Legally Marketed Devices to Which Substantial Equivalence Is Claimed**

<u>510(k) Number</u>	<u>Trade or Proprietary or Model Name</u>	<u>Manufacturer</u>
K063569	Exactech Equinox Reverse Shoulder	Exactech, Inc
K093275	Exactech Equinox Reverse Shoulder	Exactech, Inc.

**IV. Device Description**

The modifications proposed by this submission describe minor geometry changes to the standard offering of Equinox glenospheres, glenoid plates, and compression screws; these geometry modifications are the entire basis for proposed Reverse Shoulder line extensions (expanded offset glenospheres, posterior and superior augmented glenoid plates, +10mm extended cage glenoid plate, and longer compression screws).

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All proposed components are designed to interface and articulate with the Equinox Shoulder system and are supplied sterile.

**V. Indications Use**

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√		√	Humeral head fracture with displacement of the tuberosities
√	√		Pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
√	√		Revisions of humeral prostheses when other treatments or devices have failed (where adequate fixation can be achieved)
		√	Displaced three-part and four-part upper humeral fractures
	√		Spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases)
	√		Revision of failed previous reconstructions when distal anchorage is required
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The Equinox Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinox Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

The Equinox Platform Fracture Stem is indicated for use in skeletally mature individuals with acute fracture of the proximal humerus and displacement of the

**Exactech® Equinox® Reverse Shoulder™ Line Extensions**  
**Special 510(k) - Section 07 - 510(k) Summary**

tuberosities, displaced 3- and 4-part fractures of the proximal humerus (hemi-arthroplasty), or acute fracture of the proximal humerus with failure of the glenohumeral joint (primary total shoulder arthroplasty). The Equinox Platform Fracture Stem is also indicated for acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty). The Equinox Platform Fracture Stem is indicated for cemented use only.

**VI. Summary of Technological Characteristics**

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use.** Exactech Equinox Reverse Shoulder line extensions and predicate devices are intended for use in Total Shoulder Arthroplasty.
- **Materials.** Exactech Equinox Reverse Shoulder line extensions and predicate devices are composed of equivalent materials conforming to recognized industry standards for permanent implants.
- **Dimensions.** Exactech Equinox Reverse Shoulder line extensions and predicate devices are available in equivalent size ranges.
- **Sterilization processes.** Exactech Equinox Reverse Shoulder line extensions and predicate devices are provided sterile for single use and conform to recognized industry standards.
- **Performance specifications.** Exactech Equinox Reverse Shoulder line extensions and predicate devices withstand clinically relevant biomechanical loads.

**Substantial Equivalence Conclusion**

Mechanical tests, simulated-use tests, engineering analyses, and a clinical literature summary demonstrate the proposed Exactech Equinox Reverse Shoulder line extensions are substantially equivalent to the predicate devices. A summary of these tests and analyses are as follows:

- Cadaver lab validation demonstrating the design features.
- Geometric computer analysis to evaluate the relationship between the reverse shoulder design parameters and ROM, impingement, and stability.
- Dynamic test at worst case physiological load in a polyurethane bone substitute in order to evaluate initial fixation, loosening, and disassociation.
- Clinical literature summary related to cuff tear arthroplasty and reverse shoulder arthroplasty.